REMARKS/ARGUMENTS

Claims 1-16 are currently pending in the above-identified application.

Rejections Under 35 U.S.C. §112

Claims 1-16 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite, the Office suggesting it is unclear how one detects antigen-antibody complexes using an antigen which does not bind to what is said to be the only antigen present, the at least one ImCRAC antigen. Office Action, page 3.

In response, Applicants note that the ImCRAC, a cross-reactive antigen component, detects antibody that is present in the sample of the fluid being tested. The antibody that is provided as a component of the present invention does not react with the same ImCRAC, as presently recited in the claims. The antibody, however, is capable of binding to other mycobacterial antigens that may be present in the fluid sample, such as, e.g., other ImCRACs. ("The at least one antibody for a mycobacterial species with which the sample of a body fluid is contacted in accordance with the invention, can be any antibody which is capable of reacting with a certain mycobacterial antigen." (Specification, page 7, lines 28-31.)) Thus, the method and diagnostic kit are capable of detecting both antibody and antigen that may be present in the fluid sample being tested. As explained in the Specification at, e.g., page 9, lines 7-15: "[E]ither the antibody or the antigen component of these complexes will be from the body fluid. Both or just one type of these complexes may be present. The detecting of the two types of complexes can be carried out separately or together."

The possibility of detecting both antibody and antigen present in a sample increases the usefulness of such testing: "It has now been found that a highly sensitive diagnostic test can be performed by contacting a sample of a body fluid with both antibodies and antigens. It has been found that, besides antibodies, several mycobacterial components are present in animal and human body fluids, of which the presence can be determined by using cross-reactions

with a chosen set of antibodies in a reliable manner. (Specification, page 3, line 34 to page 4, line 4.") This permits in some instances both sample fluid antigen and antibody to be monitored, as in the case of therapy or even in instances of possible disease progression. ("By using the method of the invention it is possible to monitor the different stages of a treatment of a mycobacterial disease." (Page 4, lines 17-19.)) The test can also be used for speciation, as mentioned at page 9, lines 30-31, "After the analysis, the *Mycobacterium* species can be suitably identified."

Accordingly, in view of the foregoing explanation, the claims are believed to be sufficiently definite to be understood by the artisan of ordinary skill. Reconsideration of the rejection and its withdrawal are respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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